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LYON AND LYON LLP

SUITE 4700

633 WEST FIFTH STREET

LOS ANGELES CA 90071-2066

EXAMINER

LUNDGREN, J

ART UNIT

PAPER NUMBER

1653

7

DATE MAILED:

09/03/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/950,963

Applicant
Drewes et al.

Examiner
Jeffrey S. Lundgren

Group Art Unit
1653



☒ Responsive to communication(s) filed on Jun 28, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-50 is/are pending in the application.

Of the above, claim(s) 13-17 and 35 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-12, 18-34, and 36-50 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of invention I in Paper No. 6 is acknowledged (claims 1-12, 23-34, 36-50). The traversal is on the ground(s) that: it does not appear that different searches are required, and the burden to the Examiner has not been demonstrated. This is not found persuasive because the restriction Groups have required a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other groups. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of the search. Burden in examining materially different groups having materially different issues also exists.

2. Applicant's argument to the restriction of invention I (claims 1-12, 23-34, 36-50) from invention III (claims 18-22) in Paper No. 6 is acknowledged. The traversal is on the ground(s) that: the process of making is within the scope of the invention (i.e making product by hand), and that the search required for invention I and invention III do not materially differ. Based on these grounds, Examiner withdraws the restriction of invention I from invention III. The claims of

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invention I (claims 1-12, 23-34, 36-50) and invention III (claims 18-22) are rejoined, and are considered in this application.

The requirement is FINAL.

Drawings

3. This application, filed under former 37 CFR 1.60, lacks formal drawings. The informal drawings filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings. In unusual circumstances, the formal drawings from the abandoned parent application may be transferred by the grant of a petition under 37 CFR 1.182.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 18-20, 23, 24, 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Brecht et al. (Analitica Chimica Acta 311, 289-299 (1995)).

Brecht et al. teach an analytical device that determines the concentration of an analyte through an indirect, competitive immunoassay. Brecht et al. demonstrate an assay for atrazine (a

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pesticide) where the difference in antibody concentrations between the control and sample are compared when the two samples selectively bind to an atrazine modified surface. The measurement is made by detecting a change in the mass properties or refractive index of the sensing surface. The cell of Brecht et al. uses a chemically modified-glass chip that is selective to the monoclonal anti-atrazine (i.e., support, optically functional layer, channel for sample flow, attachment layer, and analyte specific receptive layer). Brecht et al. clearly teach the advantage of an assay device that delivers the sample under laminar flow conditions compared an assay device that delivers the sample under "wall jet" (plug) flow conditions (see sections 3.3 and 3.4).

Brecht et al. state (page 296):

"Results (Fig. 7 and Fig. 8) show clearly, that the signal can be increased by improvement of mass transport to the sensor surface... At least in part, the introduction of irregularities in flow characteristics affect not only the [test-to-test] reproducibility but also the noise of the binding curves."

Therefore, in the absence of convincing evidence to the contrary, the teachings of Brecht et al. meet the limitations of claims 1, 2, 18-20, 23, 24, and 36.

5. Claims 3-6, 9, 21, 22, 25, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Kline et al. (U.S. Patent No. 5,459,078, October 17, 1995).

Kline et al. disclose an assay device for the detection of digotoxin. One form of the device is described as a porous test strip material (column 25, starting with the second full paragraph), comprising nitrocellulose, which "may be any suitably absorbant, porous or capillary

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possessing material through which a solution can be transported by wicking action". Furthermore, "fluid flow through a nitrocellulose membrane is laminar and does not provide the more turbulent flow characteristics". Depending on the Reynolds number it is known that laminar efficiencies can vary, however, it is the intention of Kline et al. to produce a device that has laminar flow characteristics with the porous membrane. The non-laminar mixing conditions take place in the reagent mixing pad prior to the sample traversing the analyte receptive layer where flow is laminar. Kline et al. also disclose the integration of microparticles into the porous support, wherein the microparticles can have an attachment layer, and an analyte receptive layer. The determination of analyte in the sample can be represented to the user through a number of transduction schemes; optical (visual) methods are disclosed (column 26 lines 63-67).

Therefore, in the absence of convincing evidence to the contrary, the teachings of Kline et al, meet the limitations of claims 3-6, 9, 21, 22, 25, and 26.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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Claims 38-50 are rejected under 35 U.S.C. 102(e) as being anticipated by McGill et al. (U.S. Patent No. 5,880,552, March 9, 1999).

McGill et al. disclose a biochemical sensor device with a diamond-like coating (DLC) or diamond, an attachment layer, and an analyte receptive layer that selectively binds antigen (column 4, lines 9-32). The disclosure teaches an optical wave sensing device where the analyte is detected through a change in the optical properties of the sensor upon binding the target analyte (column 3, line 66 to column 4, line 8). McGill et al. also disclose a DLC coating on the sensor where the film thickness is between 10 and 10,000 angstroms (column 5, lines 60-64). McGill et al. disclose the method of depositing the DLC onto the sensor using a pulsed laser deposition technique, and further note that other methods may be used (column 6, lines 38-43). Therefore, in the absence of convincing evidence to the contrary, the teachings of McGill et al. meet the limitations of claims 38-50.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brecht et al. (*Analitica Chimica Acta* 311, 289-299 (1995)) in view of Goddard et al. (*Analyst* 119, 583-588, 1994).

Claim 7 is drawn to the device of claims 1, 2, 3, 4, 5, or 6, wherein said optically functional layer further comprises an antireflective layer.

Brecht et al. teach an analytical device that determines the concentration of an analyte through an indirect, competitive immunoassay. Brecht et al. demonstrate an assay for atrazine (a pesticide) where the difference in antibody concentrations between the control and sample are compared when the two samples selectively bind to an atrazine modified surface. The measurement is made by detecting a change in the mass properties or refractive index of the sensing surface. The cell of Brecht et al. uses a chemically modified-glass chip that is selective to the monoclonal anti-atrazine (i.e., support, optically functional layer, channel for sample flow, attachment layer, and analyte specific receptive layer). Brecht et al. clearly teach the advantage of an assay device that delivers the sample under laminar flow conditions compared an assay

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device that delivers the sample under "wall jet" (plug) flow conditions (see sections 3.3 and 3.4).

Brecht et al. state (page 296):

"Results (Fig. 7 and Fig. 8) show clearly, that the signal can be increased by improvement of mass transport to the sensor surface... At least in part, the introduction of irregularities in flow characteristics affect not only the [test-to-test] reproducibility but also the noise of the binding curves."

Brecht et al. do not teach the use of an antireflective layer for improved sample analysis.

Goddard et al. teach an optically-based biosensing device with improved analytical performance through integrating an antireflective coating. The resonant mirror is a planar waveguide optical sensor that uses frustrated total internal reflectance (first paragraph of page 584). Goddard et al. state (page 584):

"It has been shown that the maximum sensitivity is reached when the refractive indices of the substrate and waveguide are as high as possible, and the refractive index of the spacer is as low as possible. This combination increases the the fraction of light in the evanescent field, and hence increase the sensitivity."

From the teachings of the combined references in discipline of optical biosensing, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. One of ordinary skill in the art would have been motivated to combine the teachings of Brecht et al. and Goddard et al. as a means to improve upon the analytical performance of an optical sensor/biosensor by introducing an antireflective coating. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made.

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10. Claims 8, 10-12, 27-34, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brecht et al. (Analitica Chimica Acta 311, 289-299 (1995)) in view of Goddard et al. (Analyst 119, 583-588, 1994) as applied to claim 7 above, and further in view of Beuchler et al (U.S. Patent No. 5,458,852, October 17, 1995) and Finlan (U.S. Patent 5, 055, 265, October 8, 1991).

Repeating the aforementioned teachings of Goddard with emphasis, Goddard et al. teach a biosensing device with improved analytical performance through integrating an antireflective coating. The resonant mirror is a planar waveguide optical sensor that uses frustrated total internal reflectance (first paragraph of page 584). Goddard et al. state (page 584):

"It has been shown that the maximum sensitivity is reached when the refractive indices of the substrate and waveguide are as high as possible, and the refractive index of the spacer is as low as possible. This combination increases the the fraction of light in the evanescent field, and hence increase the sensitivity."

The arrangement that applicant has suggested in the claims that refer to the optically functional layer are met through the teachings of Goddard et al., who demonstrate the enhanced device sensitivity through the strategic arrangement of the optical layers based on refractive index. The refractive indices of amorphous silicon, silicon nitride, germanium and DLC are inherent properties of the materials, thus Goddard need not suggest the specific materials, only their arrangement based on refractive index. However, Goddard does not teach the selection of support materials or metal film attachment layer.

The reference of Beuchler et al. serves to demonstrate that the selection of materials for the support and the metal attachment layer by applicant are well known in the art of optical

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biosensors, such as SPR devices. Beuchler et al. note that the support material should be selected based on the grounds that it lends advantages to its manufacture (i.e., easily molded or machined) while still maintaining the requirements of the device (i.e., chemical properties, optical properties, etc.). Polyester and polycarbonate meet these limitations. Also, an appropriate metal attachment film should be chosen for the device. The metal film should be able to create a free plasma of metal electrons excited by a particular wavelength and angle of light (ressonance), where said ressonance is dependent upon and highly sensitive to the refractive index of the attachment layer (column 12, lines 39-51). Finlan supports the same arguments (column 2, lines 47-58). From the teachings of the combined references in discipline of optical biosensing, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. One of ordinary skill in the art would have been motivated to combine the teachings of Brecht et al. and Goddard et al. in further view of Beuchler et al. and Finlan as a means to improve upon the analytical performance of an optical sensor/biosensor by: 1) the selection and arrangement of the optically functional materials; 2) the selection of the metal attachment layer; and 3) the selection of various support materials that are workable and functional to the device. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

11. No claims are allowable.

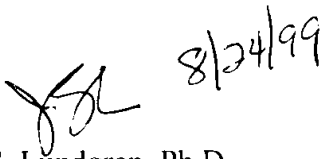
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12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeffrey S. Lundgren whose telephone number is (703) 306-3221. The Examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Bradley Sisson, can be reached at (703) 308-3978.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1653 via the PTO Fax Center using (703) 305-3014 or 305-4227. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

 8/24/99
Jeffrey S. Lundgren, Ph.D.


EGGERTON A. CAMPBELL
PRIMARY EXAMINER